

Exhibit A

**Deposition of Paul Galea
December 9, 2009**

Paul Galea
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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

- - -
IN RE: DIGITEK® PRODUCTS MDL NO. 1968
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO
ALL CASES

CONFIDENTIAL -
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -
Wednesday, December 9, 2009

- - -
Videotaped deposition of PAUL
GALEA, held at HARRIS BEACH, PLLC, 100 Wall
Street, New York, New York, commencing at
approximately 9:50 a.m., before Rosemary
Locklear, a Registered Professional Reporter,
Certified Realtime Reporter, Certified Court
Reporter (NJ) and Notary Public.

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1 Q. Was that at the request of the
2 company or had you been requesting to
3 transfer to the U.S.?

4 A. It -- it was a bit of both, I
5 could say.

6 Q. What was -- as you were
7 informed, what was the reason that the
8 company requested it, that you transfer to
9 Actavis Totowa?

10 A. The initial reason, I was doing
11 an assessment and helping out in the
12 harmonization of the group's corporate
13 manual, and that was basically the main
14 reason.

15 Q. All right. Well, let's break
16 that into two parts.

17 What was the assessment that you
18 believe that you were -- that you came here to
19 work on? Assessment of what?

20 A. Basically, I came to make an
21 assessment of Actavis Totowa, L.L.C.

22 Q. Overall assessment of the QA
23 Department?

24 A. No. In general of the company

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1 from a -- from a GMP perspective.

2 Q. Would you agree with me that
3 there was some serious GMP issues in
4 October of '07 at Actavis Totowa?

5 MR. ANDERTON: Objection.

6 You may answer.

7 THE WITNESS: How do you define
8 serious?

9 BY MR. MILLER:

10 Q. Serious? Well, there could
11 have been some GMP problems that would
12 have been, gosh, this is minor, we either
13 need to fix it or we don't need to fix it,
14 or there are some issues where if we don't
15 fix it, then we might be shut down or
16 someone might get hurt.

17 MR. ANDERTON: Objection.

18 BY MR. MILLER:

19 Q. It's okay to answer.

20 MR. ANDERTON: You may answer.

21 THE WITNESS: When I first went
22 there, that was not really the scope of my
23 assessment. My assessment was to look at the
24 company and -- and, basically, have a look at

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1 answer.

2 MR. MILLER: And why?

3 MR. ANDERTON: On the basis of
4 self-critical analysis privilege.

5 MR. MILLER: Okay.

6 BY MR. MILLER:

7 Q. Sir, we discussed the revised
8 warning letter, which you had a memory of
9 discussing in the past, but not having
10 reading.

11 And after we've gone through the
12 ten findings that were on the revised warning
13 letter, do you agree with me that the overall
14 thrust of this letter was issues with the
15 quality control and quality assurance?

16 MR. ANDERTON: Objection.

17 You may answer.

18 THE WITNESS: As written by the
19 investigator, yes, potentially they're all
20 quality issues.

21 BY MR. MILLER:

22 Q. And you agree with me that the
23 vast majority of them, nine out of ten,
24 involved GMP, good manufacturing

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1 practices.

2 MR. ANDERTON: Objection.

3 You may answer.

4 THE WITNESS: Again, as written,
5 typically, FDA would cite the GMP citations.

6 BY MR. MILLER:

7 Q. And when you had the discussion
8 about this letter, did you have an
9 understanding that there were GMP issues
10 with the quality group as a whole or was
11 it only for particular drugs?

12 MR. ANDERTON: Objection.

13 You may answer.

14 THE WITNESS: The discussion was,
15 if I can recollect, looking at the general
16 systems.

17 BY MR. MILLER:

18 Q. At the general systems.

19 So there -- you -- even when you
20 were doing your assessment, roughly the same
21 time as this letter came out, you were never
22 given any instruction or guidance to look at GMP
23 as it pertained to any particular products that
24 were being made; is that correct?

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1 MR. ANDERTON: Objection.

2 You may answer.

3 THE WITNESS: No.

4 BY MR. MILLER:

5 Q. And, in fact, the GMP at
6 Actavis Totowa, the procedures of GMP as
7 used by the quality group pertained to all
8 drugs, all products that were
9 manufactured.

10 MR. ANDERTON: Objection.

11 You may answer.

12 THE WITNESS: Procedures are not
13 product specific. Procedures tell you how to
14 perform an operation.

15 BY MR. MILLER:

16 Q. They're not product specific,
17 therefore, they apply to all products.

18 A. Procedures do not necessarily
19 apply to a product.

20 Q. Okay. Well, my question is,
21 you agree that Actavis had issues with
22 their enforcement or use of GMP in the
23 quality group in 2007.

24 MR. ANDERTON: Objection.

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1 be an issue. That is true.

2 BY MR. MILLER:

3 Q. Potentially, and if the FDA had a
4 finding such as that and put it in a warning
5 letter, more likely than not, it's an issue.

6 MR. ANDERTON: Objection.

7 You may answer.

8 THE WITNESS: Not necessarily.

9 Depending on the company's response.

10 BY MR. MILLER:

11 Q. Did GMP issues ultimately
12 result in the shutdown of production of
13 all products in August 2008 at Actavis
14 Totowa?

15 MR. ANDERTON: Objection.

16 You may answer.

17 Actually, wait. I instruct you to
18 answer only with respect to Digitek.

19 THE WITNESS: With respect to
20 Digitek, yes.

21 BY MR. MILLER:

22 Q. I'm going to hand you what I'm
23 going to mark as Exhibit 55.

24 MR. ANDERTON: Thank you.